

## REMARKS

### 1. ANALYSIS OF THE YOMTOV ET AL REFERENCE RELATIVE TO INDEPENDENT CLAIM 60

Yomtov et al teaches (Col. 10, line 61 to Col. 11 line 2) the concept of exactly two cardiac events each of which is a “*serious*” cardiac event. This is in contradistinction to the present application that teaches in the bottom paragraph of p. 26 of the present specification that two different alarms would apply to a large variety of different cardiac events which are at a different level of urgency. Of these two alarms, one is for *serious* events that are life threatening such as a heart attack or ventricular fibrillation and the other type of alarm is for a “non-emergency response” (bottom line on p. 26) for cardiac events that are *not serious* such as ischemia caused by an elevated heart rate during exercise. Yomtov et al recognizes alarms only for exactly two different types of “*serious*” events namely a “serious arrhythmic event” or a “serious ischemic event.” The present application recognizes and describes exactly two different types of alarms for exactly two different *levels of urgency* of cardiac events, namely, those that are serious which demand immediate emergency treatment and those that are not serious (i.e., non-emergency cardiac events) that can be treated at a future time that is convenient for the patient and his/her cardiologist. An alarm for non-emergency cardiac events is extremely important because it can warn a patient weeks to months before a serious condition occurs. For example, the non-emergency alarm can indicate that there is progressive narrowing (i.e., a stenosis that is getting more severe) of a coronary artery. In that case, the patient could be treated by angioplasty and/or stenting before a heart attack results from the complete closure of the coronary artery. Nowhere in the Yomtov et al reference is there any mention of alarming for non-emergency events that are not serious.

Claim 60 has now been amended to overcome the Examiner’s rejection by clearly defining the inventive concept of exactly two different types of alarms one of which is for a serious condition such as a heart attack, and the other alarm being for a non-emergency cardiac event that is not serious. Thus, claim 60 as amended

is clearly allowable over the Yomtov et al reference that only describes exactly two different serious alarms for either serious ischemia conditions or serious arrhythmias. Yomtov et al does not anticipate the need for any alarm for cardiac events that are not life threatening.

In light of the Yomtov et al reference, claim 61 has also been appropriately amended to be clearly allowable over the Yomtov et al patent. Claims 62, 64, and 67 have also been amended to better define the novel features of the present invention. Claims 61-67 should now be allowable because they are dependent upon independent claim 60 that has been amended to overcome the teachings of the Yomtov et al reference.

## **2. ANALYSIS OF THE UNGER AND THOMPSON REFERENCES RELATIVE TO CLAIM 68**

### **A) THE UNGER REFERENCE (3,724,455)**

The Unger reference describes a system that is totally external to a cardiac patient. In this system, there is an external alarm that can be triggered from a central location or from reading of the ECG from electrodes mounted onto the patient. This warning to the patient occurs if a potentially dangerous cardiac condition is observed at the central location.

### **B) THE THOMPSON REFERENCE ( 6,083,248)**

The Thompson reference teaches an implanted device that is designed to monitor a patient for a cardiac event. Thompson also teaches an external device that can receive a telemetry signal from the implanted cardiosaver device and communicate that signal to an external network for monitoring the patient.

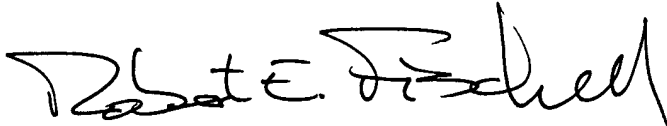
### C) ANALYSIS OF CLAIM 68 IN VIEW OF THE UNGER AND THOMPSON REFERENCES

Claim 68 is limited to systems that have 1) an implanted cardio saver device with an internal alarm to warn the patient of a cardiac event; and 2) an external alarm system that has an audio alarm that is triggered by a telemetry signal from the implanted cardio saver device when the implanted cardio saver device also creates an alarm; and 3) a network operations system that communicates with the patient by means of the external alarm system. The applicants respectfully contend that neither the Unger nor the Thompson reference teaches the combination of an implanted alarm of the implanted cardio saver device and an external audio alarm from an external alarm system that is triggered by the alarm signal from the implanted cardio saver device. An internal alarm is needed because it is the most reliable method for informing the patient that medical care is needed. This is because it is always with the patient as opposed to Unger's system with electrodes mounted on the patient's skin. Maintaining a reliable ECG signal 24 hours per day and 7 days per week from electrodes mounted on the skin is much less reliable as compared to having electrodes within the patient. For example, when the patient showers or baths, the electrodes must be removed. This is not required for the implanted system of the present invention. Furthermore, an external alarm is needed if the patient is sleeping to wake the patient up so that he/she can seek medical care. This unique combination of alarms as taught by the present invention is clearly the most reliable and effective means for informing a patient and a network operations operator, at anytime of day or night and under any circumstances that a cardiac event is occurring. To the knowledge of the applicants, no other system exists that provides both an internal alarm and an external alarm triggered by the internal alarm, which external alarm can also contact a network operations center. Since all these limitations are clearly written into claim 68, the applicants respectfully claim that claim 68 as written is allowable over the cited references.

### SUMMARY

In light of the analysis presented herein, the applicants respectfully claim that independent claims 60 and 68 are now allowable over the cited prior art. Furthermore, the applicants contend that the dependent claims 61-67 and 69-86, since they are dependent on allowable claims 60 and 68, are now in a condition for allowance. Early notice of the allowance of these claims would be very much appreciated.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert E. Fischell". The signature is fluid and cursive, with a large initial "R" and a long, sweeping underline.

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Date: June 23, 2005